UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CRIMINAL ACTION NO. 14-10363-RGS

UNITED STATES OF AMERICA

v.

KATHY S. CHIN,
MICHELLE L. THOMAS

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTIONS TO DISMISS

October 4, 2016

STEARNS, D.J.

Before the court are motions filed on behalf of defendants Kathy S. Chin and Michelle L. Thomas seeking dismissal of the indictment insofar as it alleges criminal conduct on their part. For reasons to be explained, the motions will be allowed.

On December 16, 2014, the Grand Jury returned a wide-ranging 73-page, 145-paragraph indictment alleging an assortment of crimes against fourteen defendants who are alleged to have been involved in the ownership, management, and/or operations of the now defunct New England Compounding Pharmacy, Inc. (NECC). Allegedly as the result of being administered contaminated doses of non-sterile methylprednisolone acetate (MDA) compounded by NECC, twenty-five patients died, and hundreds of

others suffered grave injuries. Kathy Chin and Michelle Thomas are described in paragraphs 13 and 14 of the indictment as Massachusetts-licensed pharmacists who "worked in the packing area checking orders prior to shipment to NECC's customers" – in Ms. Chin's case from November of 2010 until October of 2012; in Ms. Thomas's case from March of 2012 until August of 2012.[1]

The indictment is set out in six conceptually distinct chapters. The first, which encompasses Counts 1 and 2, is framed on the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961, and specifies 78 RICO racketeering acts, 25 of which allege second-degree murder. Chapter II (Count 3) charges a "*Klein*" conspiracy to defraud (mislead) the United States, or more precisely, the U.S. Food and Drug

[1] These defendants' names next appear in paragraph 119 of the indictment in which Ms. Chin is charged with four counts of unlawful dispensing and Ms. Thomas with two counts of unlawful dispensing. The ten other defendants who remain to be tried are: Barry Cadden, a licensed pharmacist and NECC's President; Glenn Chinn, also a licensed pharmacist, who oversaw NECC's "Clean Rooms"; Gene Svirskiy, Christopher Leary, and Joseph Evanovsky, licensed pharmacists who worked at various jobs in the Clean Rooms; Alla Stepanets, a pharmacist who held several positions at NECC, including working in the packing area; Sharon Carter, who served as NECC's Director of Operations; Scott Connolly, a former pharmacist who worked as a pharmacy technician; Gregory Conigliaro, NECC's regulatory compliance officer; and Robert Ronzio, NECC's national sales director. Carla Conigliaro and Douglas Conigliaro, shareholders in NECC, were charged in the same indictment with offenses unrelated to the operations of NECC.

Administration (FDA), pursuant to 18 U.S.C. § 371. Chapter III (Counts 4-56) re-alleges a number of the racketeering acts under the generic Mail Fraud Statute, 18 U.S.C. § 1341. Chapter IV (Counts 57-94) charges five defendants (Cadden, Glenn Chin, Svirskiy, Leary, and Evanovsky) with introducing adulterated or misbranded drugs into interstate commerce, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 331(a). In Chapter V (Counts 95-109), Ms. Chin and Ms. Thomas are charged with dispensing drugs (betamethasone and, in one instance, triamcinolone) in interstate commerce without a valid prescription, in violation of the FFDCA – Ms. Chin is charged in four such instances of dispensing (Counts 104-107); Ms. Thomas in two (Counts 108-109). Finally in Chapter VI (since closed), Carla Conigliaro and Douglas Conigliaro were charged with criminal contempt of a Bankruptcy Court order, 18 U.S.C. § 401(3), and the unlawful structuring of banking withdrawals, 31 U.S.C. § 5324 (Counts 110-131).

The interplay of the laws under which Ms. Chin and Ms. Thomas are indicted is complex, but their structure and wording is necessary to an understanding of this decision. Title 21 of the United States Code, Section 331(a), prohibits the introduction or causing the introduction into interstate commerce of a drug that is adulterated or misbranded. Section 353(b)(1) defines a drug capable of being misbranded as

> **(1)** A drug intended for use by man which—
>
> **(A)** because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> **(B)** is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

Section 333(a)(2), under which Ms. Chin and Ms. Thomas are charged, sets out the penalties for a violation and introduces the element of wrongful intent.

> **(a) Violation of section 331 of this title; second violation; intent to defraud or mislead**
>
> . . .
>
> **(2)** Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

Reduced to its essence, misbranding (as charged) means the dispensing of a toxic drug in interstate commerce without a (valid) prescription and with the specific intent to defraud and mislead the United States government by concealing or failing to disclose that no valid prescription had been issued. *United States v. Arlen*, 947 F.2d 139, 143 (5th Cir. 1991) (citing cases on the element of a specific intent to defraud).

In addressing a challenge to the sufficiency of an indictment, a court must determine whether the indictment "contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and . . . enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense." *Hamling v. United States*, 418 U.S. 87, 117 (1974); *see also United States v. Stewart*, 744 F.3d 17, 21 (1st Cir. 2014) (a challenge to the sufficiency of an indictment is not an opportunity to determine the sufficiency of the evidence, but rather the court will assume the truth of the indictment's factual allegations); *United States v. Guerrier*, 669 F.3d 1, 3-4 (1st Cir. 2011) (same). Typically, an indictment need only set out the charge in the words of the statute itself, so long as it does so unambiguously and provides facts "specific enough to apprise the defendant of the nature of the accusation against him and to inform the court

of the facts alleged." *United States v. Serino*, 835 F.2d 924, 929 (1st Cir. 1987).

The exact charging language of the indictment reads as follows.

> 110. From in or around December 2009 through in or around March 2012, within the District of Massachusetts and elsewhere, [Kathy Chin and Michelle Thomas], along with others known and unknown to the Grand Jury, with the intent to defraud and mislead, caused to be dispensed the drugs set forth below contrary to the provisions or Title 21, United States Code, Section 353(b)(1), in that [Kathy Chin and Michelle Thomas] caused the drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer the drugs, and the act resulted in the drugs being misbranded, each instance being a separate count in the indictment . . . . [2]

The allegations of the indictment as they relate to Ms. Chin and Ms. Thomas are sparse.

> 13. The defendant [Kathy Chin] was an individual residing in Canton, Massachusetts. Kathy Chin was a pharmacist licensed in the commonwealth of Massachusetts by the [Massachusetts Board of Registration in Pharmacy] to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about November 2010 until October 2012, Kathy Chin was

[2] It is true, as defendants argue, that the statute does not use the term "valid" prescription, but rather "written prescription." Since the drugs that Ms. Chin and Ms. Thomas shipped were described in written prescriptions issued in the names of legitimate doctors, it follows, or so defendants contend, that "they [c]ould not have violated the statute by filling a prescription they received from a licensed practitioner." Defs.' Mem. at 6 (Dkt #359). The argument is something of a damp squib. The term prescription is a medical term that describes an instruction written by, or written down from, a medical practitioner who is authorizing a patient to receive a specific medicine or treatment. The term implicitly incorporates the concept of validity.

> employed as a pharmacist at NECC. Kathy Chin worked in the packing area checking orders prior to shipment to NECC's customers.
>
> 14. The defendant [Michelle Thomas] was an individual residing in Framingham, Massachusetts. Thomas was a pharmacist licensed in the commonwealth of Massachusetts by the [Massachusetts Board of Registration in Pharmacy] to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about March 2012 until August 2012, Thomas was employed as a pharmacist at NECC. Thomas worked in the packing area checking orders prior to shipment to NECC's customers.

The only additional allegation of a quasi-factual nature referenced by the government in its pleadings is that Ms. Chin and Ms. Thomas should have known from the improbable names of some of the "patients" whose addresses they were presumably checking (which included celebrities, star athletes, and fictional characters), that no medical practitioner had issued a valid prescription authorizing the dispensing of the drugs.[3]

Assuming, as the court must in considering the motions to dismiss, that Ms. Chin and Ms. Thomas knew or should have known that at least some of the shipping labels were made out in the names of fictitious patients, does that knowledge, combined with the allegation that they worked in the

[3] Additionally, the government makes the tautological argument that Ms. Chin and Ms. Thomas were dispensing drugs, whatever role they played in the distribution process, "because the indictment clearly alleges that [they] dispensed drugs." Gov't Opp'n at 7 (Dkt #381).

packing room checking orders, fairly allege the dispensing of drugs under the FFDCA? The starting point of an answer is in the plain language of the statute. *Richardson v. United States*, 526 U.S. 813, 818 (1999). Where, as here, a word of common understanding ("dispensing") is given no further definition by Congress, it is to receive its meaning in common parlance tempered by the "commonsense concession that meaning can only be ascribed to statutory language if that language is taken in context." *Riva v. Massachusetts*, 61 F.3d 1003, 1007 (1st Cir. 1995).[4] The context here, of course, is medical pharmacology. In the world of pharmacology, a pharmacist engages in the act of dispensing when she "fill[s] a medical prescription." *Stedman's Medical Dictionary* (28th ed. 2014). In other words, a pharmacist dispenses a drug when she acts in her role as a licensed professional authorized to fill (put together) a medical prescription for delivery to a patient. Ms. Chin and Ms. Thomas are not alleged to have engaged in any conduct meeting this definition.

While not perfectly analogous, Justice Cordy, writing for a unanimous Supreme Judicial Court, made much the same point in explaining why a

[4] The applicability of this rule of statutory construction is buttressed by the fact that Congress took care in 21 U.S.C. § 321(a)-(rr) to define dozens of words, some of quite ordinary usage like "food" and "drug," without feeling the need to give a special definition to the word "dispense."

physician writing illicit prescriptions would be guilty of distributing unlawful substances, but not guilty of the separate crime of unlawfully dispensing them under state law.

> With these points in mind, several conclusions result. First, "dispensing" is overwhelmingly the act of a physician acting in an authorized manner. Pursuant to our long-standing interpretation of the structure of the Act, a physician who "dispenses" is generally exempted from prosecution under the drug statutes because the conduct is authorized. Indeed, the definition of "dispense" makes it difficult, although not impossible, to find space for illegality in the conduct. In contrast, a physician who ceases to act as a physician by transforming his office into the equivalent of a street corner or darkened alley is not exempted. The conduct involved bears no resemblance to the practice of medicine. Rather, the physician has devolved into a "pusher." *See United States v. Moore*, 423 U.S. 122, 143 (1975) ("In practical effect, [a physician issuing invalid prescriptions] acted as a large-scale 'pusher' — not as a physician"). Pushers commit the crime of "distribution." Indeed, it is impossible to conceive how a drug dealer could ever "dispense" a controlled substance. Moreover, but for a medical degree, there is nothing to distinguish the person who deals drugs from a medical office from one who does so from the street. Therefore, the physician who forfeits his exemption from prosecution by becoming a drug dealer should be prosecuted for what he is, an unlawful distributer.

Commonwealth v. Brown, 456 Mass. 708, 724 (2010) (footnote and some internal citations omitted).

In contrast to the FFDCA, the Federal Controlled Substances Act (FCSA), defines "dispense" broadly to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the

lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery." 21 U.S.C. § 802(10). This expansive definition, which includes packaging and labeling in addition to compounding, might describe defendants' conduct, but Ms. Chin and Ms. Thomas are not charged under the FCSA for the simple reason that neither betamethasone nor triamcinolone (the drugs contained in the packages they processed) are scheduled as controlled substances.

Defendants argue that if the court perceives ambiguity in the unlawful dispensing provisions of the FFDCA, it should determine whether the statute is unconstitutionally vague as applied to the conduct attributed to Ms. Chin and Ms. Thomas.[5] The void for vagueness doctrine has strong roots in considerations of fundamental due process and public policy.

> Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warnings. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen,

[5] The government (as best I can determine) is correct in stating that no court has upheld a generic vagueness challenge to the dispensing provision or other prohibitions of the FFDCA. *See* Govt's Opp'n at 8 (Dkt #381).

> judges, and juries for resolution on an *ad hoc* and subjective basis, with the attendant dangers of arbitrary and discriminatory applications.

Grayned v. City of Rockford, 408 U.S. 104, 108-109 (1972). The danger, as the Court warned in *Grayned*, is that overly aggressive and unbounded readings of statutes can produce distorted results, such as a fish being transformed into a documentary instrument, *Yates v. United States*, 135 S. Ct. 1074, 1087 (2015) (plurality opinion), or "kitchen cupboard" chemical irritants into chemical weapons banned under international law, *Bond v. United States*, 134 S. Ct. 2077, 2093 (2014), or a constituent courtesy into a corrupt official act, *McDonnell v. United States*, 136 S. Ct. 2355, 2372-2373 (2016).

Here the issue, however, is not ambiguity. The statute as written clearly punishes pharmacists who fill or take part in the filling of invalid prescriptions placed into interstate commerce with the intent to defraud or mislead the government. What the FFDCA does not reach is conduct incidental to the distribution of a prescribed drug (in contrast to the FCSA), such as "checking a package," or taking it to the extreme, picking it up for delivery. Returning to basics, the issue in this case is one of fair notice. Would a reasonable person, even a reasonable pharmacist, understand from the indictment that by matching orders to packages prior to their being

shipped, she was criminally liable for participating in the filling of a prescription that she had never approved (or is even alleged to have seen), and as a result was guilty of dispensing (misbranding) the prescribed drug with the intent to defraud? The answer, as best as I can determine, is that she would not. Absent allegations of conduct amounting to fair notice of a crime under the FFDCA, the indictment fails.[6]

ORDER

For the foregoing reasons, the motions to dismiss Counts 104-107, and 108-109 as they relate to Ms. Chin and Ms. Thomas are ALLOWED.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

[6] To be clear, the court is not saying that the defendants may not have violated some law, just not the law the government has chosen to invoke.